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| 09/733,775 | 12/08/2000 | Hans A. Mische | | 2947 |

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| EXAMINER |
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PATEL, NIHIR B

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| ART UNIT | PAPER NUMBER |
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3772

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06/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/733,775

Applicant(s)

MISCHE, HANS A.

Examiner

Nihir Patel

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 21st, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 3-8, 11, 14, 15 and 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9, 10, 12, 13, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03.29.2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of **Group 1 (Figures 1A and 1B; claims 1, 2, 9, 10, 12, 13, 16 and 17)** in the reply filed on March 21st, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The petition was granted and the abandonment dated July 21st, 2004 is withdrawn.
3. Claims **3-8, 11, 14, 15 and 18-24** are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 1st, 2002.

Specification

4. The disclosure is objected to because of the following informalities: The specification is not 1.5 or double-spaced.

Appropriate correction is required.

5. The claims are objected to because the lines are crowded too closely together, making reading difficult. Substitute claims with lines one and one-half or double spaced on good quality paper are required. See 37 CFR 1.52(b).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims **1, 2, 9 and 16** are rejected under 35 U.S.C. 102(e) as being anticipated by Reiley et al. (US 6,248,110).

8. As to **claim 1**, Reiley discloses systems and methods for treating fractured or diseased bone using expandable bodies that comprises an expandable device **56 (see figures 4 and 5J; column 6 lines 45-50)** for occupying space within bones (**see figure 5J**); a means of expanding the device (**see column 8 lines 25-35**); whereby the expanded device mechanically fixates the fracture (**see column 8 lines 40-50**).

9. As to **claim 2**, Reiley teaches an apparatus wherein the means of expanding the device is an inflatable catheter (**see figure 4; column 6 lines 40-50**).

10. As to **claim 9**, Reiley teaches an apparatus wherein the expanded device joins separated bone segments (**see column 8 lines 40-50**).

11. As to **claim 16**, As to **claim 1**, Reiley discloses systems and methods for treating fractured or diseased bone using expandable bodies that comprises an expandable tubular device **56 (see figures 4 and 5J; column 6 lines 45-50)**; a delivery device (**see column 8 lines 25-35**); the tubular device attached to delivery device, whereby the delivery device expands the tubular device at treatment site, whereby the expanded device joins bone segment (**see column 8 lines 40-50**).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims **10, 12, 13 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al. (US 6,248,110).

15. **As to claims 10, 12 and 13**, Reiley substantially discloses method steps comprising utilizing an expandable device for occupying space within a bone segment (**see figure 5J**); creating an access hole in bone (**see figure 5J**); disposing the structure upon a delivery device; inserting the structure within the bone segment (**see figure 5J**); advancing the structure to the desired location within the bone segment (**see figure 5J**); activating a portion of the delivery device in order to cause expansion of the structure (**see column 8 lines 40-50**).

The claimed method steps would have been obvious because they would have resulted from the use of the device of Reiley.

16. **As to claim 17**, Reiley substantially discloses the claimed invention, see rejection of claim 16 above, but does not disclose a delivery device being a tubular mesh. It would have been an obvious matter of design choice to have a delivery device being a tubular mesh in order to hold the fractured bone together, since the applicant has not disclosed that having a delivery

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device being a tubular mesh solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with using filling material as taught by Reiley.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Nihir Patel

Patricia Bianco
PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
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6/11/07

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